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RUEHGV/USMISSION GENEVA 1776

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STATE PASS USTR
STATE FOR EAP/TC,
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E.O. 12958: N/A
TAGS: [ECON](#) [ETRD](#) [EIND](#) [TW](#)
SUBJECT: TAIWAN PHARMACEUTICALS: PVS RESULTS ANNOUNCED,
WITH NO SURPRISES

REF: A. TAIPEI 3275 TAIPEI 2947

[1](#)B. TAIPEI 2570

Summary and Introduction

[1](#)1. On September 28, the Bureau of National Health Insurance announced the results of the fifth Price Volume Survey, with price cuts effective November 1. Pricing information for individual companies will be sent out Monday, October 2, and companies will have two weeks to appeal. BNHI President Liu Chien-hsiang briefed AIT on the results the day before the announcement. The results mostly reflect changes previously discussed during consultations (ref A). Generic grouping will be done based on the 2003 model. BNHI has no plans to implement therapeutic grouping. According to BNHI, modifications to the PVS will increase reimbursements to multinational drug firms by about US\$ 186 million. Of course much of this will be passed back to hospitals in additional discounts. See action request in paragraph 8.

The Fifth PVS - Mostly Sticking to Earlier Concessions

[1](#)2. Many of the announced modifications have already been reported:

-- Merck Index 1983 will determine patent term for pricing purposes. Originally BNHI intended to use Merck Index 1984. Industry and USG had been pushing for Merck Index 1982.

--The R-zone (the amount of "reasonable discount") remains at 15% for patented drugs.

--Angio-tension receptor blocker (ARB) drugs will not be subject to groupings, but will be reclassified as patented drugs for related adjustments - a change that will benefit 15 innovative drugs of six companies.

--Nineteen categories of drugs, including EPO and insulin, on which the original R&D companies maintain competitiveness, will not be subject to price adjustments. This will influence the prices of 188 drugs of 16 companies.

¶3. In addition to the drugs mentioned in earlier discussions, BNHI added three other pharmaceutical products - albumin, blood factor 8, and blood factor 9, which will not be subject to price adjustments. BNHI is also establishing floor prices for categories of drugs - injections at NT\$10 per dose, liquids at NT\$20, and DOH-standard packaged tablets at NT\$1.5.

¶4. The following is a complete list of drugs that will be exempt from price cuts:

Dactinomycin Injection
Phenobarbital Sodium single active ingredient injection
Biperiden Lactate injection
Verapamil HCL injection
Phenylephrine HCL injection
Digoxin tablet
L-Asparaginase injection
Penicillin G injection
Streptomycin injection
Azthioprine tablet
Murine monoclonal antibody CD3 (=Muromonal CD3) injection
Blood products: Immunoglobulin, Blood Coagulation factors 8 and 9 for human use
Atropine single active ingredient products
Insulin Products
Epoetin products
Peritoneal dialysis solution
Drugs for treating T.B.
Compound active ingredients injection containing 10% Calcium Gluconate and 0.35% Calcium Sacchrate
Protamine Sulfate single active ingredient injection

Generic Grouping

¶5. The Fifth PVS reverts to a grouping model akin to that used in 2003. Off-patent branded drugs are grouped with BA/BE generics (i.e. generics tested against the original

drug for bioavailability and bioequivalence). In this grouping, the group weighted average price (or "GWAP" in industry parlance) for off-patent branded drugs will be multiplied by a factor of 1.05 to preserve a gap between these drugs and their BA/BE generic equivalents. Simple generics will be grouped separately.

Moving on Standard Contract, Thinking about Working Groups

¶6. Longer term, BNHI reported that they are moving ahead on developing a standard contract and are planning meetings with various stakeholders on the issue. Dr. Liu was reluctant to give a timeline, stating that he was unsure if legislation would need to be adopted to implement a standard contract. He also stressed the importance of training and education opportunities for the Department of Health and the BNHI staff as they work towards long-term reforms. Dr. Liu reiterated his willingness to set up working groups on the issues of actual transaction pricing, separation of prescribing and dispensing, and standard contracts. He asked the USG to provide its views on how these working groups should be constituted.

No therapeutic grouping for the next 3 years -guaranteed

¶7. AIT again expressed interest in the two new drug pricing cases where therapeutic grouping seems to be a factor in setting the price, both of which are being appealed. Dr. Liu stated emphatically that no therapeutic grouping would be imposed for at least the next three years. After that, he couldn't promise, since it was unlikely that he would still be at BNHI.

Action Request:

¶8. Post requests guidance on how to move forward on the working groups suggested by DAUSTR during the September 13 digital video conference.

WANG